

J. Peter KLEIN et al.
Appl. No. 09/288,556
January 29, 2004

REMARKS/ARGUMENTS

Claims 1-7 and 10-29 are pending in this application. Claim 28 stands withdrawn from further consideration as not being readable on the elected species. Claims 1, 3, 4, 21 and 26-29 are amended to encompass infringing subject matter. Applicants reserve the right to file continuing applications for canceled or non-elected subject matter. No new matter has been added.

IMPROPER MARKUSH REJECTION

The Office Action rejects claims 1-7 and 10-25 under non-statutory grounds as allegedly being improper Markush claims in the definitions of X, Y, Z and R₁ variables. The Examiner suggests amending the claims to recite the elected species where X and Y are N, Z is C(R₃), and R₁ is a substituted or unsubstituted C₍₅₋₉₎ hydroxyalkyl would overcome the rejection. In response, Applicants respectfully submit that the Examiner's characterization of the election is erroneous and lacks a statutory basis. However, solely in an effort to advance prosecution and without acquiescing in the legality of the rejection, Applicants have amended claim 1 in an attempt to provide a common heterocyclic core moiety, as suggested in the Office Action. Applicants reserve the right to file divisional applications for any non-elected species not encompassed by the amended claims. The rejection is overcome.

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Office Action rejects claims 1-7 and 10-25 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because the proviso clause recites that R₁ is not an ω-1 alcohol

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substituted C₁₋₃ alkyl group, yet R₁ is defined as being C₍₅₋₉₎ hydroxyalkyl group. In response, Applicants respectfully submit that the objected to terminology does not exist in the proviso clause. See Second Supplemental Amendment filed on January 31, 2003. This aspect of the rejection is moot.

The Office Action further objects to the location in the claim of the phrase "including resolved enantiomers, diastereomers, tautomers, salts and solvates thereof". The Office Action states that this phrase should be at the end of the claim and not contain the term "including." In response, Applicants respectfully submit that the position of the objected to phrase does not render the claim indefinite within the meaning of 35 U.S.C. § 112, second paragraph. The proper inquiry under the second paragraph of § 112 is merely to determine whether the claims set out and circumscribe a particular area with a reasonable degree of precision and particularity. *In re Moore*, 169 U.S.P.Q. 236, 238 (C.C.P.A. 1971). Applicants respectfully submit that the rejected claims are clear and precise such that a skilled artisan could readily understand their scope. Indeed, an informal search of the USPTO's patent database reveals claims with similar language in a similar location in at least the following granted U.S. patents:

U.S. Patent No. 6,586,429	U.S. Patent No. 5,801,182
U.S. Patent No. 6,133,274	U.S. Patent No. 5,780,476
U.S. Patent No. 6,103,730	U.S. Patent No. 5,777,117
U.S. Patent No. 6,100,271	U.S. Patent No. 5,777,115
U.S. Patent No. 6,043,250	U.S. Patent No. 5,750,575
U.S. Patent No. 6,020,337	U.S. Patent No. 5,641,783
U.S. Patent No. 5,824,677	U.S. Patent No. 5,473,070
U.S. Patent No. 5,817,662	U.S. Patent No. 5,340,813
U.S. Patent No. 5,807,862	U.S. Patent No. 5,288,721
U.S. Patent No. 5,804,584	

Accordingly, reconsideration and withdraw of this rejection are respectfully requested.

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REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 1-7, 10-27 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hinze (U.S. Patent No. 4,515,795). The Office Action asserts that the R₁ containing compounds include the simple alkyl homologs and position isomers of the compounds disclosed in Hinze. Applicants respectfully traverse this rejection.

The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention under any statutory provision always rests on the PTO. *In re Mayne*, 104 F.3d 1339, 41 USPQ2d 1451 (Fed. Cir. 1997); *In re Oetiker*, 977 F. 2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). Here, Applicants respectfully submit that the Office Action has not met its burden. Compounds falling within the scope of the presently claimed invention are not mere adjacent homologs that form a part of a series that differ from the compounds disclosed in Hinze by the successive addition of the same chemical moiety. Nor are the claimed compounds, as a whole, so closely similar in structure that one of ordinary skill in the art would have expected the compounds to have similar properties. On the contrary, Applicants respectfully submit that Hinze merely discloses that dimethylxanthines containing a longer chain hydroxyalkyl group (4-8, preferably 5-8 carbon atoms) in any of the 1-3 or 7-positions possess improved properties as compared to prior known hydroxypropyl compounds because they *act to improve cerebral blood flow*. Column 1, lines 28-33. The compounds disclosed in Hinze comprise dimethylxanthine bound to R₁, R₂, and R₃ groups that are either branched or unbranched ω - or (ω -1)-hydroxyalkyl groups. At column 4, lines 50-68 and column 6, lines 52-59, Hinze merely discloses/enables compounds wherein 6 carbon atoms or less is the largest separation between the carbon atom onto which the hydroxyl is bound and a xanthine nucleus. *See, e.g.*, the 1-(7-hydroxyoctyl)-3,7-dimethylxanthine compound disclosed at column 4, lines 54-55 and the Examples.

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The Office Action has failed to point to any teaching in Hinze or provide any cogent technical reason explaining the basis for the erroneous conclusion that the presently claimed invention would have been *prima facie* obvious. *Ex parte Mowry*, 91 U.S.P.Q. 219 (BPAI 1947). Hinze conspicuously does not teach or suggest compounds having the specific substituents of the claimed compounds, let alone having the same properties or characteristics that enable them to be useful for a variety of clinical indications mediated at the cellular level by IL-12 signaling, as in the claimed invention. Further, Hinze does not disclose or suggest any compound having an R₁ being a ω-1-hydroxyalkyl group while at the same time providing an R₃ group other than hydrogen or a simple alkyl and R₄ group other than hydrogen. Simply stated, Hinze does not teach, suggest or provide any motivation to one of ordinary skill in the art to reach the compounds of the claimed invention.

At best, Hinze merely invites experimentation of compounds having a hydroxyl group more than 6 carbon atoms removed from a xanthine nucleus. Invitation to experiment, however, is not the standard of obviousness. In ascertaining the differences between the prior art and the claims at issue, it is essential to view the claims "without the benefit of hindsight vision afforded by the claimed invention." *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n. 5, 229 U.S.P.Q. 182, 187 n. 5 (Fed. Cir. 1986). The prior art must suggest the desirability and thus the obviousness of making the combination without the slightest recourse to the teachings of the patent or application. Without such independent suggestion, the prior art is to be considered merely to be inviting experimentation which is not the standard with which obviousness is determined. *In re Laskowski*, 871 F.2d 115, 117, 10 U.S.P.Q.2d 1397, 1398 (Fed. Cir. 1989); *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1532 (Fed. Cir. 1988); *In re*

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Gordon, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1985); *In re Regel*, 526 F.2d 1399, 1403 n. 6, 188 U.S.P.Q. 136, 139 n. 6 (C.C.P.A. 1975).

Thus, reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a) are respectfully requested.

CONCLUSION

If anything further could be done to place the above-captioned patent application in better condition for allowance (i.e., via Examiner's Amendment), please contact the undersigned attorney at the telephone number below.

Please grant any extension of time deemed necessary. The Commissioner is hereby authorized to charge any deficiency in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to Deposit Account No. 14-1140. Please credit any overpayments to such Deposit Account.

Respectfully submitted,

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